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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
10/015,394	12/11/2001	Kevin P. Baker	39780-2830P1C41	9887
7590 10/17/2005			EXAMINER	
Ginger R Dreger			BUNNER, BRIDGET E	
Heller Ehrman White & McAuliffe LLP 275 Middlefield Road			ART UNIT	PAPER NUMBER
Menlo Park, CA 94025			1647	

DATE MAILED: 10/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Application No. Applicant(s) **Advisory Action** 10/015.394 BAKER ET AL. Before the Filing of an Appeal Brief Examiner Art Unit Bridget E. Bunner 1647 --The MAILING DATE of this communication appears on the cover sheet with the correspondence address --THE REPLY FILED 03 June 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. 1. X The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods: a) The period for reply expires \_\_\_\_ \_\_months from the mailing date of the final rejection.

MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO

event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

earned patent term adjustment. See 37 CFR 1.704(b).
NOTICE OF APPEAL
2. The Notice of Appeal was filed on <u>08 September 2005</u> . A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).
<u>AMENDMENTS</u>
3. The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will <u>not</u> be entered because  (a) They raise new issues that would require further consideration and/or search (see NOTE below);  (b) They raise the issue of new matter (see NOTE below);
(c)∐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) They present additional claims without canceling a corresponding number of finally rejected claims. NOTE: (See 37 CFR 1.116 and 41.33(a)).
4. The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  5. Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
6. Newly proposed or amended claim(s) would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. For purposes of appeal, the proposed amendment(s): a) will not be entered, or b) will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: Claim(s) objected to: Claim(s) rejected: <u>28-32</u> . Claim(s) withdrawn from consideration:
AFFIDAVIT OR OTHER EVIDENCE
8. The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will <u>not</u> be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will <u>not</u> be entered because the affidavit or other evidence failed to overcome <u>all</u> rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.  REQUEST FOR RECONSIDERATION/OTHER
11. The request for reconsideration has been considered but does NOT place the application in condition for allowance because: <u>See Continuation Sheet.</u>
12. Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s)

Continuation of 5. Applicant's reply has overcome the following rejection(s): The rejection of claims 28 and 31 under 35 USC 101 (claimed invention is directed to non-statutory subject matter) is withdrawn in view of the amended claim.

Continuation of 11. does NOT place the application in condition for allowance because:

Claims 28-32 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well established utility. Applicant's arguments (03 June 2005), as they pertain to the rejections have been fully considered but are not deemed to be persuasive for the following reasons.

Applicant asserts that one of skill in the art would readily understand that a protein which inhibits glucose uptake into adipocytes is a potential therapeutic target, since blocking the function of this protein would decrease the inhibition, and thus increase glucose uptake into adipocytes. Applicant argues that one of skill in the art would further understand that antagonists to the PRO1760 polypeptide include antibodies and that accordingly, the claimed antibodies are useful in the therapeutic treatment of disorders wherein stimulation of glucose uptake by adipocytes is expected to be therapeutically effective, such as obesity, diabetes, and hyperor hypo-insulinemia. Applicant's arguments have been fully considered but are not found to be persuasive. The proposed use of the PRO1760 polypeptides and the claimed PRO1760 antibodies that bind the polypeptide as potential therapeutic targets is simply a starting point for further research and investigation into potential practical uses of the polypeptides and antibodies.

Applicant also contends that Mueller et al. (1998) disclose that inhibitors of adipocyte glucose uptake inhibit leptin gene expression and leptin secretion from adipocytes. Applicant argues that one of skill in the art would have understood that agents capable of modulating leptin regulation would be useful in investigations regarding the treatment of obesity. Applicant states that PRO1760, as an inhibitor, would be useful as a pharmacological tool for invesigation of leptin regulation. Applicant's arguments have been fully considered but are not found to be persuasive. The specification of the instant application does not teach that PRO1760 is involved in leptin regulation. Furthermore, the proposed use of the claimed PRO1760 polypeptides and antibodies as a potential therapeutic tools to investigate leptin regulation is simply a starting point for further research and investigation into potential practical uses of the polypeptides and antibodies.

The polynucleotide, polypeptide, and antibody do not have a substantial utility because basic research is required to study the properties and activity of the polynucleotide that encodes the polypeptide of SEQ ID NO: 376. Until some actual and specific significance can be attributed to the protein identified in the specification as PRO1760, the instant invention is incomplete. In the absence of knowledge of the biological significance of this protein, there is no immediately obvious patentable use for it. If the specification discloses nothing specific and substantial about the PRO1760 polypeptide, therefore both the polypeptide and its antibodies have no patentable utilities. Since the instant specification does not disclose a "real world" use for PRO1760 then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

Claims 28-32 and 39-40 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Applicant states that a specific and substantial asserted utility has been disclosed, as described above. Specifically, since Applicant has not provided evidence to demonstrate that the PRO1760 polypeptide has a specific and substantial asserted utility or a well established utility, one skilled in the art would not know how to use the claimed invention. It is noted that the instant specification is required to teach one skilled in the art how to make and use the PRO1760 polypeptide and antibody.

ELIZABETH KEMMERER PRIMARY EXAMINER